Ex-10

EXHIBIT 10

IND LOG

SubType: IND

CI#: 376 Sub Date: 7/18/88

Generic: Appr Date:

Product Name: Estrostep

Barcode	Ser/ Ref#	Date / To: / From:	RE/ Report Title/ Report No. / Contents/Report No./
B03104	0	Mon, Jul 18, 1988	Initial IND
			Volumes = 1 - Birth control Item 1: Introductory Statement and General Investigational Plan Item 2: Investigator's Brochure Item 3: PR. 376-364-001 Item 4: Chemistry, Manufacturing and Control Information A) Drug Substance/Drug Product B) Drug Label C) Environmental Assessment Claim for Exclusion Item 5: Pharmacology and Toxicology Information Item 6: Previous Human Experience With the Investigational Drugs
B03104		Tue, Jul 26, 1988	FDA Letter Acknowledging Receipt (IND 31,861)
			Acknowledgement of receipt of IND on 26-Jul-88; number 31, 861 assigned.
B03104		Mon, Aug 29, 1988	FDA Letter RE: Approval
			FDA approval to proceed and request for additional information.
B03104	1	Fri, Sep 23, 1988	Protocol Amendment (New Investigator & Change in Protocol)
			PR. 376-364-002: PR. 376-364-003: PR. 376-364-005: Amendment #1: PR. 376-364-001: 8-Aug-88: Changes the wording on Page 5 D. 11.
B03104	2	Wed, Sep 28, 1988	Letter RE: Response to Request for Information
			Response to 28-Aug-88 request for information: 1) Patient diary 2) Patient consent 3) Bulk shipping label
B03104	3	Wed, Sep 28, 1988	Protocol Amendment (New Investigators)
			PR. 376-364-006: PR. 376-364-007:
B03104	4	Mon, Oct 10, 1988	Letter RE: Response to Request for Information
			Further definition of breakthrough bleeding and spotting.

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B03104	5	Thu, Oct 20, 1988	Protocol Amendment (New Investigators & Change in Protocol)
			PR. 376-364-004: PR. 376-364-008: The New Investigator's Summary Page for 376-364, Centers 6 and 7 was inadvertently left out. Cross reference: SN #003
B03104	6	Tue, Jan 17, 1989	Protocol Amendment (New Investigator)
			PR. 376-364-005:
B03104	7	Fri, Mar 10, 1989	Safety Report
			Patient #: 79 (PLC) PR. 376-364-004: AE: Ruptured ovarian cyst Possibly drug related. AE #: None
B03104	8	Wed, Mar 29, 1989	Protocol Amendment (New Investigator)
			PR. 376-364-006:
B03104	9	Mon, Apr 10, 1989	Letter RE: Response to Request for Information
		S. Sobel, MD	Response to FDA request for further information on Dr. Eaton R. Philip, MD (PR. 376-364-006) qualifications.
B03104	10	Fri, Apr 21, 1989	Safety Report
			Patient #: 33 (BDH) PR. 376-364-004 AE: Ovarian cyst, nausea, vomiting, ovarian pain Possibly drug related AE #: 001-0376-890004
B03104	11	Fri, Apr 28, 1989	Protocol Amendment (New Investigators)
			PR. 376-364-002: PR. 376-364-005:
B03104	12	Wed, May 31, 1989	Letter RE: Request for Information
		S. Sobel	Request review and comments on PR. 376-369 (ultrasound).

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B03104	13	Thu, Jul 06, 1989 S. Sobel	Letter RE: Request for Meeting Requested meeting to discuss IND 26,445 and 31,861 and NDA 17-354 and 16-723. FDA meeting shall be held 20-Jul-89 at 10 am.
B03104	14	Tue, Aug 01, 1989	Protocol Amendment (New Investigator) PR. 376-369-000:
B03104	15	Fri, Aug 04, 1989	Minutes of FDA Meeting 20-Jul-89 - FDA meeting to discuss bioavailability.
B03104		Thu, Aug 24, 1989	FDA Letter RE: PR. 376-369 PR. 376-369 is satisfactory.
B03104	16	Wed, Sep 27, 1989	Minutes of FDA Meeting 15-Sep-89: FDA meeting to discuss bioavailability.
B03104	17	Wed, Oct 18, 1989 S. Sobel	Letter RE: Agenda for pre-NDA meeting 24-Oct-89 pre-NDA meeting agenda.
B03104	18	Fri, Oct 27, 1989	Annual Report Cutoff date: 19-Oct-89
B03104		Tue, Nov 07, 1989 S. Sobel	FDA Letter RE: Request for information Additions/comments regarding minutes of the 15-Sep-89 bioavailability/bioequivalence meeting.
B03104	19	Wed, Nov 29, 1989	Minutes of FDA Meeting 24-Oct-89: FDA meeting regarding pre-NDA.
B03104	20	Fri, Dec 22, 1989	Protocol Amendment (New Investigator) PR. 376-376-000:
B03105	21	Mon, Jan 22, 1990	Protocol Amendment (New Investigator) PR. 376-374-001:

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B03105	22	Mon, Feb 05, 1990		Protocol Amendment (New Investigator)
			PR. 376-374-006:	
B03105	23	Mon, Feb 12, 1990		Protocol Amendment (New Investigator)
			PR. 376-374-002:	
B03105	24	Mon, Feb 19, 1990		Protocol Amendment (New Investigator)
			PR. 376-374-004: PR. 376-374-008:	
B03105	25	Mon, Mar 12, 1990		Protocol Amendment (New Investigator)
			PR. 376-374-007:	
B03105	26	Thu, Mar 15, 1990		Letter RE: Request for Information
		S. Sobel	Request approval for the following pertaining to NDA submission: 1) Draft tables 2) Case report tabulations	
B03105	27	Fri, Mar 30, 1990		Letter RE: Response to Request for Information
		S. Sobel	26-Mar-90 telephone coversation regarding Dr. R. Young's CV.	
B03105	28	Mon, Apr 23, 1990		Protocol Amendment (New Investigator)
			PR. 376-374-005:	
B03105	29	Mon, May 14, 1990		Letter RE: Response to request for information
		S. Sobel	Response to FDA request for information. Randomization of patients for PR. 376-374.	
B03105	30	Wed, Jun 06, 1990		Protocol Amendment (Change in Protocol)
			Amendment #1: PR. 376-374-002 and PR. 376-374-007 (only): 1-May-90: Increases the total enrollment by 14.	
B03105	31	Fri, Jul 27, 1990		Letter RE: General Correspondence to FDA
		S.Sobel	CI-376: Preparing NDA for Estrostep; request meeting with FDA to discuss formulation development and bioequivalence study requirements.	

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B03105	32	Tue, Jul 31, 1990	Annual Report / IB Update Issue Date: 27-Jul-90 (1)Research Reports submitted. Refer to Research Report list for RR #, date, author and title.
B03105	33	Tue, Aug 07, 1990	Protocol Amendment (New Investigator) PR. 376-379-000: J.C. Kisicki, MD PR. 376-378-000: P. Wicht, MD
B03105		Tue, Sep 18, 1990 M. Taylor	FDA Letter RE: NDA for CI-376 Meeting for NDA is not needed because: 1) We have not provided clinical data for the tablet to be marketed. 2) We must provide results of the bioequivalence study that compares tablets used in the clinical trials to tablets that we plan to market.
B03105	34	Fri, Sep 21, 1990	Information Amendmend (Pharmacology/Toxicology) (1) Research Reports submitted. Refer to Research Report list for RR #, date, author and title.
B03105	35	Tue, Oct 09, 1990	Protocol Amendment (Change in Protocol) Amendment #2: PR. 376-374-007: 01-Aug-90: Allows for an increase in patients from 28 to 56 for this site of this Multi-Center study.
B03106	36	Mon, Nov 26, 1990	Information Amendment (Clinical) (1) Research Reports submitted. Refer to Research Report list for RR #, date, author and title.
B03107	37	Mon, Jan 07, 1991	Protocol Amendment (New Investigator) PR. 376-374-002: S.A. Pasquale, MD
B03107	38	Mon, Mar 11, 1991	Protocol Amendment (New Investigators) PR. 376-374-002: L.M. Scheininger
B03108	39	Mon, Jun 03, 1991	Information Amendment (Clinical) (1) Research Reports submitted. Refer to Research Report list for RR #, date, author and title.

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B03108	40	Fri, Aug 16, 1991	Annual Report
			Issue Date: 15-Aug-91 Reporting Period: 25-Jul-90 through 19-Jul-91
B03108		Mon, Mar 23, 1992	Memo RE: Preclinical Testing
		Distribution	Letter sent to P-D, in Dec-87, regarding the preclinical testing of contraceptive steroids. A copy of the letter was given to us by FDA on 20-Mar-92.
		M. Taylor	
B03108	41	Thu, Apr 16, 1992	Information Amendment (Pharmacology/Toxicology)
			(1) Research Report submitted. Refer to Research Report list for RR #, date, author and title. RR 724-00152: The market-image tablets used in this study were of a developmental nature and will not be used in the future. Pharmacokinetics sample analyses were not performed.
B03108	42	Wed, Sep 23, 1992	Annual Report
			Date: 23-Sep-92 Periods Covered: 20-Jul-91 through 3-Jun-92
B03109	43	Mon, Nov 08, 1993	Information Amendment: Clinical
		S. Sobel	Issue Date: 05/11/92 (1) Research Report submitted. Refer to Research Report list for RR# , date, author and title.
		M. Taylor	
B06494	44	Tue, Nov 09, 1993	Annual Report
		S. Sobel	Reference is made to our IND 31,861 for Estrostep® (norethindrone acetate and ethinyl estradiol) Tablets. Since the last Annual Report was submitted on September 23, 1992 (Serial No. 042), we have no new information to report at this time. We submitted a clinical study report for Study 376-374 (RR-995-00013), November 8, 1993 (Serial No. 043). This study was summarized in the last annual report. No clinical studies are ongoing, however, we wish to keep this IND open for future clinical work.
		M. Taylor	

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B06494	45	Fri, Sep 09, 1994	Annual Report
		S. Sobel	Reference is made to our IND 31,861 for Estrostep® (norethindrone acetate and ethinyl estradiol) Tablets. Since the last Annual Report was submitted on November 9, 1993 (Serial No. 044), we have no new information to report at this time. No clinical studies are ongoing, however, we wish to keep this IND open for future clinical work.
		M. Taylor	
B06494	46	Fri, Aug 25, 1995	Annual Report
		S. Sobel	Reference is made to our IND 31,861 for Estrostep® (norethindrone acetate and ethinyl estradiol) Tablets. Since the last Annual Report was submitted on September 9, 1994 (Serial No. 045), we have no new information to report at this time. No clinical studies are ongoing, however, we wish to keep this IND open for future clinical work.
		M .Taylor	
B06494	47	Fri, Aug 30, 1996	Annual Report
		S. Sobel	Annual Report
		M. Taylor	